House Bill 455 (COMMITTEE SUBSTITUTE)

By: Representative Stephens of the 164th

A BILL TO BE ENTITLED

AN ACT

To amend Chapter 13 of Title 16 of the Official Code of Georgia Annotated, relating to controlled substances, so as to enact the "Georgia Prescription Monitoring Program Act"; to provide for legislative intent; to provide for definitions; to provide for the establishment of a program for the monitoring of prescribing and dispensing Schedule II, III, or IV controlled substances by the Georgia State Board of Pharmacy; to require dispensers to submit certain information regarding the dispensing of certain drugs; to provide for the confidentiality of submitted information except under certain circumstances; to authorize the Georgia Drugs and Narcotics Agency to contract for services relating to the program; to provide for the establishment of a Prescription Monitoring Program Advisory Committee; to provide for its membership, duties, and organization; to provide for the establishment of rules and regulations; to provide for penalties; to provide for limited liability; to provide for related matters; to provide for an effective date; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

Chapter 13 of Title 16 of the Official Code of Georgia Annotated, relating to controlled substances, is amended by adding a new article to read as follows:

"ARTICLE 6

16-13-120.

This article shall be known and may be cited as the 'Georgia Prescription Monitoring Program Act.'

16-13-121.

This article is intended to improve the state's ability to identify and stop diversion of prescription drugs in an efficient and cost-effective manner that will not impede the

appropriate medical utilization of licit controlled substances or other licit drugs with potential for abuse while minimizing impact on pharmacy operations.

16-13-122.

(a) As used in this article, the term:

(1) 'Agency' means the Georgia Drugs and Narcotics Agency.

(2) 'Board' means the Georgia State Board of Pharmacy.

(3) 'Controlled substance' has the same meaning given such term in paragraph (4) of Code Section 16-13-21.

(4) 'Dispenser' means a person who delivers a Schedule II, III, or IV controlled substance to the ultimate user but shall not include:

(A) A licensed pharmacy of a hospital that dispenses such substances for the purpose of inpatient or outpatient hospital care, a licensed pharmacy of a hospital or retail pharmacy of a hospital which dispenses prescriptions for controlled substances at the time of dismissal or discharge from such a facility, or a licensed pharmacy of a hospital or retail pharmacy of a hospital which dispenses such substances for long-term care patients or inpatient hospice facilities;

(B) An institutional pharmacy that serves only a health care facility, including, but not limited to, a nursing home, an intermediate care home, a personal care home, or a hospice program, which provides inpatient care and which pharmacy dispenses such substances to be administered and used by a patient on the premises of the facility;

(C) A practitioner or other authorized person who administers such a substance; or

(D) A pharmacy operated by, on behalf of, or under contract with the Department of Corrections for the sole and exclusive purpose of providing services in a secure environment to prisoners within a penal institution, penitentiary, prison, detention center, or other secure correctional institution. This shall include correctional institutions operated by private entities in this state which house inmates under the Department of Corrections.

A hospital, clinic, or other health care facility may apply to the board for an exemption to be excluded from the definition of this term for purposes of compliance with this article if compliance would impose an undue hardship on such facility. The board shall provide guidelines and criteria for what constitutes an undue hardship which shall include criteria relating to the amount of indigent patients served and the lack of electronic capability of the facility.

(5) 'Patient' means the person or animal who is the ultimate user of a drug for whom a prescription is issued or for whom a drug is dispensed.

(6) 'Prescriber' means a physician, dentist, veterinarian, scientific investigator, or other person licensed, registered, or otherwise authorized under the laws of this state to prescribe, distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state.

(7) 'Schedule II, III, or IV controlled substance' means a controlled substance that is classified as a Schedule II, III, or IV controlled substance under Code Section 16-13-26, 16-13-27, or 16-13-28, respectively, or under the Federal Controlled Substances Act, 21 U.S.C. Section 812.

16-13-123.

(a) The board and agency may apply for available grants and accept any gifts, grants, or donations to assist in developing and maintaining the program established by this article.

(b) The board shall be authorized to grant funds to dispensers for the purpose of covering costs for dedicated equipment and software for dispensers to use in complying with the reporting requirements of this article. Such grants shall be funded by gifts, grants, donations, or other funds appropriated for the operation of the prescription monitoring program. The board shall be authorized to establish standards and specifications for any equipment and software purchased pursuant to a grant received pursuant to this article. Nothing in this article shall be construed to require a dispenser to incur costs to purchase equipment and software used to comply with this article.

16-13-124.

(a) The board shall establish and maintain a program for the monitoring of prescribing and dispensing of all Schedule II, III or IV controlled substances.

(b) Each dispenser shall submit to the board by electronic means information regarding each prescription dispensed for a drug included under subsection (a) of this Code section. The information submitted for each prescription shall include, but not be limited to:

(1) United States Drug Enforcement Administration (DEA) permit number or approved dispenser facility identification number;

(2) Date prescription filled;

(3) Prescription number;

(4) Whether prescription is new or a refill;

(5) National Drug Code (NDC) for drug dispensed;

(6) Quantity dispensed;

(7) Number of days´ supply of the drug;

(8) Patient´s name;

(9) Patient´s address;

(10) Patient´s date of birth;

(11) Approved prescriber identification number;

(12) Date prescription issued by prescriber; and

(13) Other data elements consistent with standards established by the American Society for Automation in Pharmacy, if designated by regulations of the board.

(c) Each dispenser shall submit the information in accordance with transmission methods and frequency requirements established by the board but no less often than weekly and shall report, at a minimum, prescriptions dispensed up to the day prior to data submission.

(d) The board may issue a waiver to a dispenser that is unable to submit prescription information by electronic means acceptable to the board. Such waiver may permit the dispenser to submit prescription information by paper form or other means, provided all information required in subsection (b) of this Code section is submitted in this alternative format subject to the frequency requirements of subsection (c) of this Code section. Requests for waivers shall be submitted in writing.

16-13-125.

(a) Prescription information submitted to the board shall be confidential and shall not be subject to open records requirements, as contained in Article 4 of Chapter 18 of Title 50, except as provided in subsections (c) and (d) of this Code section.

(b) The board shall establish and maintain strict procedures to ensure that the privacy and confidentiality of patients and prescribers and patient and prescriber information collected, recorded, transmitted, and maintained pursuant to this article are protected. Such information shall not be disclosed to persons except as otherwise provided in this Code section and only in a manner which in no way would conflict with the requirements of the federal Health Insurance Portability and Accountability Act of 1996, P.L. 104-191. This may include, but not be limited to, restricting access only to those individuals and entities which clearly demonstrate a need to know such information.

(c) The board shall review the prescription information and if there is reasonable cause to believe a violation of law or breach of professional standards may have occurred, the board shall notify the appropriate law enforcement or professional licensing, certification, or regulatory agency or entity and shall provide prescription information to such agency or entity which may be necessary for an investigation.

(d) The board shall be authorized to provide data collected pursuant to this article to the following persons or under the following circumstances:

(1) Persons authorized to prescribe or dispense controlled substances for the purpose of providing medical or pharmaceutical care for their patients;

(2) Upon the request of a person about whom the information requested concerns or upon the request on his or her behalf by his or her attorney;

(3) The Composite State Board of Medical Examiners or any licensing board whose practitioners have the authority to prescribe or dispense controlled substances;

(4) Local, state, and federal law enforcement or prosecutorial officials engaged in the administration, investigation, or enforcement of the laws governing licit drugs;

(5) Upon the lawful order of a court of competent jurisdiction; and

(6) Personnel of the agency for purposes of administration and enforcement of this article, Article 2 of this chapter, the 'Georgia Controlled Substances Act,' or any other applicable state law.

(e) The board may provide data to public or private entities for statistical, research, or educational purposes after removing information that could be used to identify prescribers or individual patients or persons who received prescriptions from dispensers.

(f) Any person who receives data or reports from the board shall not provide such data or reports to any other person or entity except by order of a court of competent jurisdiction or as otherwise permitted pursuant to this article.

16-13-126.

The agency shall be authorized to contract with another state agency or with a private vendor, as necessary, to ensure the effective operation of the prescription monitoring program established pursuant to this article. Any contractor shall be bound to comply with the provisions regarding confidentiality of prescription information in Code Section 16-13-125 and shall be subject to the penalties specified in Code Section 16-13-129 for unlawful acts.

16-13-127.

(a) There is established a Prescription Monitoring Program Advisory Committee for the purposes of consulting with and advising the board and the agency on matters related to the establishment, maintenance, and operation of the prescription monitoring program established pursuant to this article. This shall include, but not be limited to, data collection, regulation of access to data, and security of data collected.

(b) The advisory committee shall consist of five members, appointed by the board, which may include individuals representing pharmacies, dentistry, and medical professionals. The board shall be authorized, but not required, to make such appointments from recommendations submitted by the Medical Association of Georgia, the Georgia Dental Association, the Georgia Pharmacy Association, and the Georgia Society of Health System

Pharmacies. Each member of the advisory committee shall serve a two-year term and until the appointment and qualification of such member´s successor.

(c) The advisory committee shall elect a chairperson and vice chairperson from among its membership to serve a term of one year.

(d) The advisory committee shall meet at the call of the chairperson or upon request by at least three of the members and shall meet at least one time per year. Three members of the committee shall constitute a quorum.

(e) The members shall receive no compensation or reimbursement of expenses from the state for their services as members of the advisory committee.

16-13-128.

The board shall promulgate rules and regulations setting forth the procedures and methods for implementing this article.

16-13-129.

(a) A dispenser who willfully and intentionally fails to submit prescription monitoring information to the board as required by this article or willfully and intentionally submits incorrect prescription information shall be guilty of a misdemeanor and punished by imprisonment for a period not to exceed 12 months or a fine not to exceed $1,000.00, or both.

(b) A person authorized to have prescription monitoring information pursuant to this article who willfully and intentionally discloses such information in violation of this article shall be guilty of a felony and punished by imprisonment for a period not to exceed ten years or a fine not to exceed $10,000.00, or both.

(c) A person authorized to have prescription monitoring information pursuant to this article who willfully and intentionally uses such information in a manner or for a purpose in violation of this article shall be guilty of a felony and punished by imprisonment for a period not to exceed ten years or a fine not to exceed $10,000.00, or both.

(d) The penalties provided by this Code section are intended to be cumulative of other penalties which may be applicable and are not intended to repeal such other penalties.

16-13-130.

Nothing in this article shall require a dispenser or prescriber to obtain information about a patient from the prescription monitoring program established pursuant to this article. A dispenser or prescriber shall not have a duty and shall not be held liable for damages to any person in any civil, criminal, or administrative action for injury, death, or loss to person or property on the basis that the dispenser or prescriber did or did not seek or obtain

information from the prescription monitoring program. A dispenser or prescriber acting in good faith shall be immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for requesting or receiving information from the prescription monitoring program."

SECTION 2.

This Act shall be effective on July 1, 2008.

SECTION 3.

All laws and parts of laws in conflict with this Act are repealed.